

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO**

**IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION**

Case No. 2:18-md-2846

**CHIEF JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson**

**This document relates to:
ALL CASES**

**ANSWER AND DEFENSES OF
DEFENDANTS DAVOL INC. AND C. R. BARD, INC. TO
MASTER LONG FORM COMPLAINT**

Defendants Davol Inc. and C. R. Bard, Inc., (“Defendants”) by and through counsel,
answer the Master Long Form Complaint (the “Master Complaint”) as follows:

I. PARTIES

PLAINTIFFS

1. Paragraph 1 of the Master Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 1 of the Master Complaint and therefore deny the same.

2. Paragraph 2 of the Master Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Master Complaint and therefore deny the same.

DEFENDANTS

3. Davol Inc. (“Davol”) admits that it is a subsidiary of C. R. Bard, Inc. (“Bard”).
Davol also admits that it is incorporated in Delaware with its principal place of business in

Rhode Island. Davol admits that it focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy. Davol further admits that it conducts, at certain times, design, limited manufacturing, marketing, and sale of its products. Davol does not know what is meant by “research,” “development,” “testing,” “production,” and “promotion” beyond the meanings of design, manufacturing, marketing, and sale, which have been addressed above. Davol denies the remaining allegations as phrased.

4. Davol denies Paragraph 4 of the Master Complaint as phrased. Davol further states that at certain times it conducted limited manufacturing of some of its hernia repair products in Rhode Island.

5. Davol admits that it has communicated with the FDA related to its hernia repair products and that some of those communications may have come from Rhode Island.

6. Davol admits that its marketing efforts are managed from its principal place of business in Rhode Island.

7. C. R. Bard, Inc. (“Bard”) admits that it is organized under the laws of the State of New Jersey and that Davol is its subsidiary. Bard is a multinational developer, manufacturer and marketer of medical devices in vascular, urology, oncology and surgical specialty areas. Bard denies the remaining allegations, as phrased.

8. The allegations in Paragraph 8 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 8 of the Master Complaint.

9. The allegations in Paragraph 9 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 9 of the Master Complaint.

10. The allegations in Paragraph 10 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 10 of the Master Complaint.

11. The allegations in Paragraph 11 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 11 of the Master Complaint.

II. JURISDICTION AND VENUE

12. Defendants admit this court has subject matter jurisdiction.

13. Defendants do not know what is meant by “the federal judicial jurisdiction” and therefore cannot properly respond. Bard denies that this Court has personal jurisdiction over it based on the allegations in the Master Complaint. The specific jurisdiction analysis for Davol and Bard would depend on the allegations and state of residence of each Plaintiff identified in the Short Form Complaint for each case. As to the remaining allegations in Paragraph 13 of the Master Complaint, they are conclusions of law and no answer is required, but to the extent an answer is required, Defendants deny the same.

14. Defendants do not know what is meant by “the federal judicial jurisdiction” and therefore cannot properly respond. A venue analysis would depend on information contained in each Short Form Complaint for each case. As to the remaining allegations in Paragraph 14 of the Master Complaint, they are conclusions of law and no answer is required, but to the extent an answer is required, Defendants deny the same.

III. FACTS COMMON TO ALL COUNTS

“DAVOL/BARD HERNIA MESH DEVICES”

15. Defendants admit that at various times either Bard or Davol designed, distributed, manufactured, and sold the 3DMax™ Light Mesh, 3DMax™ Mesh, Bard® Mesh Dart, Bard®

Mesh (formally known as Marlex), Composix™ Mesh, Composix™ E/X Mesh, Composix® Kugel® Hernia Patch, Composix™ L/P Mesh, Kugel® Hernia Patch, Modified Kugel® Hernia Patch, PerFix™ Plug, PerFix™ Light Plug, SpermaTex™ Mesh, Ventralight™ ST Mesh, Ventralex™ Hernia Patch, Ventralex™ ST Hernia Patch, Ventrío™ Hernia Patch, Ventrío™ ST Hernia Patch, and Visilex™ Mesh. Davol admits that at various times it distributed, manufactured, and sold, the Sepramesh™ IP Composite. The description of each product from its marketing materials speaks for itself. Defendants deny the remaining allegations in Paragraph 15 of the Master Complaint.

16. Defendants admit that United States Food and Drug Administration (“FDA”), through Section 510(k) of the Food, Drug and Cosmetic Act, cleared the 3DMax™ Light Mesh, 3DMax™ Mesh, Bard® Mesh Dart, Composix™ Mesh, Composix™ E/X Mesh, Composix® Kugel® Hernia Patch, Composix™ L/P Mesh, Kugel® Hernia Patch, Modified Kugel® Hernia Patch, PerFix™ Plug, PerFix™ Light Plug, SpermaTex™ Mesh, Ventralight™ ST Mesh, Ventralex™ Hernia Patch, Ventralex™ ST Hernia Patch, Ventrío™ Hernia Patch, Ventrío™ ST Hernia Patch, Visilex™ Mesh, and Sepramesh™ IP Composite for use by prescribing physicians in accordance with their accompanying labeling information. As to Bard® Mesh, Defendants deny the allegations as phrased. Bard® Mesh was legally marketed in the United States before May 28, 1976, and thus is a pre-amendment device. The 510(k) process speaks for itself. Defendants deny that “no formal review for safety or efficacy was ever conducted for the Hernia Mesh Devices” and that “[t]he 510(k) process is not a formal review for safety or efficacy.”

“POLYPROPYLENE IN HERNIA MESH DEVICES: DEFECTS & RISKS”

17. Defendants admit that the products identified in the Master Complaint contain in part polypropylene. Defendants deny the remaining allegations in Paragraph 17 of the Master Complaint.

18. The MSDS sheets referred to in Paragraph 18 of the Master Complaint speak for themselves. To the extent material allegations are alleged, Defendants deny those allegations.

19. Defendants deny the allegations in Paragraph 19 of the Master Complaint.

20. Defendants deny the allegations in Paragraph 20 of the Master Complaint, including subparts (a) through (m).

21. Defendants deny the allegations in Paragraph 21 of the Master Complaint.

22. Defendants deny the allegations in Paragraph 22 of the Master Complaint.

23. Defendants deny the allegations in Paragraph 23 of the Master Complaint.

24. Defendants deny the allegations in Paragraph 24 of the Master Complaint.

“DEFENDANTS’ ACTS & OMISSIONS REGARDING THEIR DEFECTIVE DEVICES”

25. Defendants admit that at various times either Bard or Davol designed, distributed, manufactured, and sold the 3DMax™ Light Mesh, 3DMax™ Mesh, Bard® Mesh Dart, Bard® Mesh (formally known as Marlex), Composix™ Mesh, Composix™ E/X Mesh, Composix® Kugel® Hernia Patch, Composix™ L/P Mesh, Kugel® Hernia Patch, Modified Kugel® Hernia Patch, PerFix™ Plug, PerFix™ Light Plug, SpermaTex™ Mesh, Ventralight™ ST Mesh, Ventralex™ Hernia Patch, Ventralex™ ST Hernia Patch, Ventrío™ Hernia Patch, Ventrío™ ST Hernia Patch, and Visilex™ Mesh for use by prescribing physicians in accordance with their instruction for use. Davol admits that at various times it distributed, manufactured, and sold, the Sepramesh™ IP Composite for use by prescribing physicians in accordance with their instruction for use. Defendants do not know what is meant by “producing,” “testing,” “studying,” “inspection,” “labeling,” “marketing,” “advertising,” and “promoting,” besides what is admitted above. Defendants deny the remaining allegations in Paragraph 25 of the Master Complaint.

26. Defendants deny the allegations in Paragraph 26 of the Master Complaint.

27. Defendants deny the allegations in Paragraph 27 of the Master Complaint.

28. Defendants deny the allegations in Paragraph 28 of the Master Complaint.
29. Defendants deny the allegations in Paragraph 29 of the Master Complaint.
30. Defendants deny the allegations in Paragraph 30 of the Master Complaint.
31. Defendants deny the allegations in Paragraph 31 of the Master Complaint.
32. Defendants deny the allegations in Paragraph 32 of the Master Complaint.
33. Defendants deny the allegations in Paragraph 33 of the Master Complaint.
34. Defendants deny the allegations in Paragraph 34 of the Master Complaint.
35. Defendants deny the allegations in Paragraph 35 of the Master Complaint.
36. Defendants deny the allegations in Paragraph 36 of the Master Complaint.
37. Defendants deny the allegations in Paragraph 37 of the Master Complaint.
38. Defendants deny the allegations in Paragraph 38 of the Master Complaint.
39. Defendants deny the allegations in Paragraph 39 of the Master Complaint.
40. Defendants deny the allegations in Paragraph 40 of the Master Complaint,

including subparts (a) through (p)

41. Defendants admit that instructions for use are provided with the 3DMax™ Light Mesh, 3DMax™ Mesh, Bard® Mesh Dart, Bard® Mesh (formally known as Marlex), Composix™ Mesh, Composix™ E/X Mesh, Composix® Kugel® Hernia Patch, Composix™ L/P Mesh, Kugel® Hernia Patch, Modified Kugel® Hernia Patch, PerFix™ Plug, PerFix™ Light Plug, SpermaTex™ Mesh, Ventralight™ ST Mesh, Ventralex™ Hernia Patch, Ventralex™ ST Hernia Patch, Ventrío™ Hernia Patch, Ventrío™ ST Hernia Patch, Visilex™ Mesh, and Sepramesh™ IP Composite. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegation that “[t]he Hernia Mesh Devices were at all times utilized

and implanted in a manner foreseeable to Defendants.” Defendants deny the remaining allegations in Paragraph 41 of the Master Complaint.

42. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 42 of the Master Complaint and therefore deny the same.

43. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 43 of the Master Complaint and therefore deny the same.

“ADDITIONAL DEFECTS: CERTAIN HERNIA MESH DEVICES”

44. Defendants deny the allegations in Paragraph 44 of the Master Complaint.

45. Defendants deny the allegations in Paragraph 45 of the Master Complaint.

46. Defendants admit that hernia products with “ST” contain Sepra® Technology.

Defendants also admit that Sepramesh™ IP Composite contains Sepra® Technology.

Defendants deny the remaining allegations in Paragraph 46 of the Master Complaint.

“ST DEVICES’: ADDED DEFECTS & RISKS”

47. Defendants deny the allegations in Paragraph 47 of the Master Complaint.

48. Defendants deny the allegations in Paragraph 48 of the Master Complaint.

49. Defendants deny the allegations in Paragraph 49 of the Master Complaint.

50. Defendants deny the allegations in Paragraph 50 of the Master Complaint,

including all subparts

51. Defendants deny the allegations in Paragraph 51 of the Master Complaint.

52. Defendants deny the allegations in Paragraph 52 of the Master Complaint.

53. Defendants deny the allegations in Paragraph 53 of the Master Complaint.

54. Defendants deny the allegations in Paragraph 54 of the Master Complaint.

“DEFENDANTS’ ACTS & OMISSIONS REGARDING ‘ST DEVICES’”

55. Defendants deny the allegations in Paragraph 55 of the Master Complaint.

56. Defendants deny the allegations in Paragraph 56 of the Master Complaint.

57. Defendants deny the allegations in Paragraph 57 of the Master Complaint.

58. Defendants deny the allegations in Paragraph 58 of the Master Complaint.

59. Defendants deny the allegations in Paragraph 59 of the Master Complaint.

60. Defendants deny the allegations in Paragraph 60 of the Master Complaint.

“ePTFE DEVICES”: ADDED DEFECTS & RISKS”

61. Defendants deny the allegations in Paragraph 61 of the Master Complaint.

62. Defendants deny the allegations in Paragraph 62 of the Master Complaint.

63. Defendants deny the allegations in Paragraph 63 of the Master Complaint.

64. Defendants deny the allegations in Paragraph 64 of the Master Complaint.

65. Defendants deny the allegations in Paragraph 65 of the Master Complaint.

66. Defendants deny the allegations in Paragraph 66 of the Master Complaint.

67. Defendants deny the allegations in Paragraph 67 of the Master Complaint.

68. Defendants deny the allegations in Paragraph 68 of the Master Complaint.

69. Defendants deny the allegations in Paragraph 69 of the Master Complaint.

70. Defendants deny the allegations in Paragraph 70 of the Master Complaint.

71. Defendants deny the allegations in Paragraph 71 of the Master Complaint.

“DEFENDANTS’ ACTS & OMISSIONS REGARDING “ePTFE DEVICES”

72. Defendants deny the allegations in Paragraph 72 of the Master Complaint, including subparts (a) through (h).

73. Defendants deny the allegations in Paragraph 73 of the Master Complaint.

74. Defendants deny the allegations in Paragraph 74 of the Master Complaint, as phrased.

75. Defendants deny the allegations in Paragraph 75 of the Master Complaint.

76. Defendants deny the allegations in Paragraph 76 of the Master Complaint.

77. Defendants deny the allegations in Paragraph 77 of the Master Complaint.

78. Defendants deny the allegations in Paragraph 78 of the Master Complaint.

79. Defendants deny the allegations in Paragraph 79 of the Master Complaint.

80. Defendants deny the allegations in Paragraph 80 of the Master Complaint.

81. Defendants deny the allegations in Paragraph 81 of the Master Complaint.

82. Defendants deny the allegations in Paragraph 82 of the Master Complaint.

83. The October 6, 2002, complaint referred to in Paragraph 83 of the Master Complaint speaks for itself.

84. The April 14, 2003, email referred to in Paragraph 84 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

85. The January 2002, survey referred to in Paragraph 85 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

86. David Paolo's testimony referred to in Paragraph 86 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

87. Stephen Clarke's testimony referred to in Paragraph 87 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

88. Jim Keegan's testimony referred to in Paragraph 88 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

89. The January 7, 2002, patent application referred to in Paragraph 89 of the Master Complaint speaks for itself.

90. Thomas Swanson's testimony referred to in Paragraph 90 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

91. The DaVinci studies referred to in Paragraph 91 of the Master Complaint speak for themselves. To the extent any material allegations are alleged, those are denied.

92. The FDA's 2006 Establishment Inspection Report referred to in Paragraph 92 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

93. Defendants deny the allegations in Paragraph 93 of the Master Complaint.

94. The FDA's 2006 Establishment Inspection Report referred to in Paragraph 94 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

95. Defendants deny the allegations in Paragraph 95 of the Master Complaint.

96. Defendants deny the allegations in Paragraph 96 of the Master Complaint.

97. The FDA's definition of a Class 1 recall speaks for itself.

98. Defendants admit that certain sizes of the Composix Kugel Hernia Patches were voluntarily recalled due to the memory recoil ring being broken by physicians who were aggressively bending and manipulating the patches during implantation, including folding the patches inappropriately along the short axis. Defendants deny the remaining allegations in Paragraph 98 of the Master Complaint.

99. The FDA's 2006 Establishment Inspection Report referred to in Paragraph 99 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

100. Defendants admit that in March 2006 Davol expanded the recall to Composix Kugel models 202 and 204 manufactured before January 2004 and model 209 manufactured before March 2006.

101. Defendants admit that in January 2007 Davol expanded the recall and/or withdrew lots of large patches manufactured between January 2004 and September 2005. Defendants deny the remaining allegations in Paragraph 101 of the Master Complaint.

102. The April 24, 2007, FDA “Warning Letter” referred to in Paragraph 102 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

103. The BioAssist report referred to in Paragraph 103 of the Master Complaint speaks for itself. To the extent any material allegations are alleged, those are denied.

104. Defendants deny the allegations in Paragraph 104 of the Master Complaint.

105. Defendants deny the allegations in Paragraph 105 of the Master Complaint.

DISCOVERY RULE; STATUTORY OR EQUITABLE TOLLING; ESTOPPEL

106. The allegations in Paragraph 106 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 106 of the Master Complaint.

107. The allegations in Paragraph 107 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 107 of the Master Complaint.

108. The allegations in Paragraph 108 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 108 of the Master Complaint.

109. The allegations in Paragraph 109 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 109 of the Master Complaint.

110. The allegations in Paragraph 110 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 110 of the Master Complaint.

IV. COUNTS

COUNT I

STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN

111. In response to Paragraph 111 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

112. The allegations in Paragraph 112 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 112 of the Master Complaint.

113. The allegations in Paragraph 113 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 113 of the Master Complaint.

114. The allegations in Paragraph 114 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 114 of the Master Complaint.

115. The allegations in Paragraph 115 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 115 of the Master Complaint.

116. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 116 of the Master Complaint and therefore deny the same.

117. The allegations in Paragraph 117 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 117 of the Master Complaint.

118. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 118 of the Master Complaint and therefore deny the same.

119. The allegations in Paragraph 119 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 119 of the Master Complaint.

120. The allegations in Paragraph 120 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 120 of the Master Complaint.

121. The allegations in Paragraph 121 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 121 of the Master Complaint.

122. The allegations in Paragraph 122 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 122 of the Master Complaint.

123. The allegations in Paragraph 123 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 123 of the Master Complaint.

124. The allegations in Paragraph 124 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 124 of the Master Complaint.

125. The allegations in Paragraph 125 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 125 of the Master Complaint.

COUNT II
STRICT PRODUCT LIABILITY: FAILURE TO WARN

126. In response to Paragraph 126 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

127. Davol admits that it manufactured and distributed the 3DMax™ Light Mesh, 3DMax™ Mesh, Bard® Mesh Dart, Bard® Mesh (formally known as Marlex), Composix™ Mesh, Composix™ E/X Mesh, Composix® Kugel® Hernia Patch, Composix™ L/P Mesh, Kugel® Hernia Patch, Modified Kugel® Hernia Patch, PerFix™ Plug, PerFix™ Light Plug, SpermaTex™ Mesh, Ventralight™ ST Mesh, Ventralex™ Hernia Patch, Ventralex™ ST Hernia Patch, Ventrío™ Hernia Patch, Ventrío™ ST Hernia Patch, and Visilex™ Mesh for use by prescribing physicians in accordance with its accompanying labeling information. Davol admits that at various times it conducted limited manufacturing of, and distributed the Sepramesh™ IP Composite. Bard denies the remaining allegations in Paragraph 127 of the Master Complaint.

128. The allegations in Paragraph 128 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 128 of the Master Complaint.

129. The allegations in Paragraph 129 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 129 of the Master Complaint.

130. The allegations in Paragraph 130 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 130 of the Master Complaint.

131. The allegations in Paragraph 131 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 131 of the Master Complaint.

132. The allegations in Paragraph 132 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 132 of the Master Complaint.

133. The allegations in Paragraph 133 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 133 of the Master Complaint.

134. The allegations in Paragraph 134 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 134 of the Master Complaint.

135. The allegations in Paragraph 135 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 135 of the Master Complaint.

136. The allegations in Paragraph 136 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 136 of the Master Complaint.

137. The allegations in Paragraph 137 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 137 of the Master Complaint.

138. The allegations in Paragraph 138 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 138 of the Master Complaint.

139. The allegations in Paragraph 139 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 139 of the Master Complaint.

140. The allegations in Paragraph 140 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 140 of the Master Complaint.

141. The allegations in Paragraph 141 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 141 of the Master Complaint.

142. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 142 of the Master Complaint and therefore deny the same.

143. The allegations in Paragraph 143 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 143 of the Master Complaint.

144. The allegations in Paragraph 144 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 144 of the Master Complaint.

145. The allegations in Paragraph 145 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 145 of the Master Complaint.

146. The allegations in Paragraph 146 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 146 of the Master Complaint.

147. The allegations in Paragraph 147 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 147 of the Master Complaint.

COUNT III
STRICT PRODUCT LIABILITY: MANUFACTURING DEFECT

148. In response to Paragraph 148 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

149. The allegations in Paragraph 149 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 149 of the Master Complaint.

150. The allegations in Paragraph 150 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 150 of the Master Complaint.

151. The allegations in Paragraph 151 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 151 of the Master Complaint.

152. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 152 of the Master Complaint and therefore deny the same.

153. The allegations in Paragraph 153 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 153 of the Master Complaint.

154. The allegations in Paragraph 154 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 154 of the Master Complaint.

155. The allegations in Paragraph 155 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 155 of the Master Complaint.

156. The allegations in Paragraph 156 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 156 of the Master Complaint.

157. The allegations in Paragraph 157 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 157 of the Master Complaint.

158. The allegations in Paragraph 158 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 158 of the Master Complaint.

**COUNT IV
NEGLIGENCE**

159. In response to Paragraph 159 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

160. The allegations in Paragraph 160 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 160 of the Master Complaint.

161. The allegations in Paragraph 161 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 161 of the Master Complaint.

162. The allegations in Paragraph 162 of the Master Complaint, including subparts (a) through (w) are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 162 of the Master Complaint, including subparts (a) through (w).

163. The allegations in Paragraph 163 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 163 of the Master Complaint.

164. The allegations in Paragraph 164 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 164 of the Master Complaint.

165. The allegations in Paragraph 165 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 165 of the Master Complaint.

166. The allegations in Paragraph 166 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 166 of the Master Complaint.

167. The allegations in Paragraph 167 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 167 of the Master Complaint.

168. The allegations in Paragraph 168 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 168 of the Master Complaint.

169. The allegations in Paragraph 169 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 169 of the Master Complaint.

170. The allegations in Paragraph 170 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 170 of the Master Complaint.

**COUNT V
NEGLIGENCE PER SE**

171. In response to Paragraph 171 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

172. The allegations in Paragraph 172 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 172 of the Master Complaint.

173. The allegations in Paragraph 173 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 173 of the Master Complaint.

174. The allegations in Paragraph 174 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 174 of the Master Complaint.

175. The allegations in Paragraph 175 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 175 of the Master Complaint.

176. The allegations in Paragraph 176 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 176 of the Master Complaint.

177. The allegations in Paragraph 177 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 177 of the Master Complaint.

178. The allegations in Paragraph 178 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 178 of the Master Complaint.

COUNT VI GROSS NEGLIGENCE

179. In response to Paragraph 179 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

180. The allegations in Paragraph 180 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 180 of the Master Complaint.

181. The allegations in Paragraph 181 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 181 of the Master Complaint.

182. The allegations in Paragraph 182 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 182 of the Master Complaint.

183. The allegations in Paragraph 183 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 183 of the Master Complaint.

184. The allegations in Paragraph 184 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 184 of the Master Complaint.

**COUNT VII
STATE CONSUMER PROTECTION LAWS**

185. In response to Paragraph 185 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

186. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 186 of the Master Complaint or those allegations are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 186 of the Master Complaint.

187. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 187 of the Master Complaint and therefore deny the same.

188. The allegations in Paragraph 188 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 188 of the Master Complaint.

189. The allegations in Paragraph 189 of the Master Complaint, including subparts (a) through (c) are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 189 of the Master Complaint, including subparts (a) through (c).

190. The allegations in Paragraph 190 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 190 of the Master Complaint.

191. The allegations in Paragraph 191 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 191 of the Master Complaint.

192. The allegations in Paragraph 192 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 192 of the Master Complaint.

193. The allegations in Paragraph 193 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 193 of the Master Complaint.

194. The allegations in Paragraph 194 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 194 of the Master Complaint.

195. The allegations in Paragraph 195 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 195 of the Master Complaint.

196. The allegations in Paragraph 196 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 196 of the Master Complaint.

197. The allegations in Paragraph 197 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 197 of the Master Complaint.

198. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 198 of the Master Complaint and therefore deny the same.

199. The allegations in Paragraph 199 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 199 of the Master Complaint.

200. The allegations in Paragraph 200 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 200 of the Master Complaint.

COUNT VIII BREACH OF IMPLIED WARRANTY

201. In response to Paragraph 201 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

202. Defendants admit that either Bard or Davol sold the 3DMax™ Light Mesh, 3DMax™ Mesh, Bard® Mesh Dart, Bard® Mesh (formally known as Marlex), Composix™ Mesh, Composix™ E/X Mesh, Composix® Kugel® Hernia Patch, Composix™ L/P Mesh,

Kugel® Hernia Patch, Modified Kugel® Hernia Patch, PerFix™ Plug, PerFix™ Light Plug, SpermaTex™ Mesh, Ventralight™ ST Mesh, Ventralex™ Hernia Patch, Ventralex™ ST Hernia Patch, Ventrio™ Hernia Patch, Ventrio™ ST Hernia Patch, and Visilex™ Mesh for use by prescribing physicians in accordance with its accompanying labeling information. Davol admits that at various times it sold the Sepramesh™ IP Composite for use by prescribing physicians in accordance with its accompanying labeling information. Defendants deny the remaining allegations in Paragraph 202 of the Master Complaint.

203. The allegations in Paragraph 203 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 203 of the Master Complaint.

204. The allegations in Paragraph 204 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 204 of the Master Complaint.

205. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 205 of the Master Complaint and therefore deny the same.

206. The allegations in Paragraph 206 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 206 of the Master Complaint.

207. The allegations in Paragraph 207 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 207 of the Master Complaint.

208. The allegations in Paragraph 208 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 208 of the Master Complaint.

**COUNT IX
BREACH OF EXPRESS WARRANTY**

209. In response to Paragraph 209 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

210. The allegations in Paragraph 210 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 210 of the Master Complaint.

211. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 211 of the Master Complaint and therefore deny the same.

212. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 212 of the Master Complaint and therefore deny the same.

213. The allegations in Paragraph 213 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 213 of the Master Complaint.

214. The allegations in Paragraph 214 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 214 of the Master Complaint.

215. The allegations in Paragraph 215 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 215 of the Master Complaint.

COUNT X
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

216. In response to Paragraph 216 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

217. The allegations in Paragraph 217 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 217 of the Master Complaint.

218. The allegations in Paragraph 218 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 218 of the Master Complaint.

219. The allegations in Paragraph 219 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 219 of the Master Complaint.

220. The allegations in Paragraph 220 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 220 of the Master Complaint.

COUNT XI
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

221. In response to Paragraph 221 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

222. The allegations in Paragraph 222 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 222 of the Master Complaint.

223. The allegations in Paragraph 223 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 223 of the Master Complaint.

224. The allegations in Paragraph 224 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 224 of the Master Complaint.

COUNT XII
NEGLIGENT MISREPRESENTATION

225. In response to Paragraph 225 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

226. The allegations in Paragraph 226 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 226 of the Master Complaint.

227. The allegations in Paragraph 227 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 227 of the Master Complaint.

228. The allegations in Paragraph 228 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 228 of the Master Complaint.

229. The allegations in Paragraph 229 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 229 of the Master Complaint.

230. The allegations in Paragraph 230 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 230 of the Master Complaint.

231. The allegations in Paragraph 231 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 231 of the Master Complaint.

232. The allegations in Paragraph 232 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 232 of the Master Complaint.

233. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 233 of the Master Complaint and therefore deny the same.

234. The allegations in Paragraph 234 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 234 of the Master Complaint.

235. The allegations in Paragraph 235 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 235 of the Master Complaint.

COUNT XIII FRAUD AND FRAUDULENT MISREPRESENTATION

236. In response to Paragraph 236 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

237. Defendants admit that at various times either Bard or Davol designed, manufactured, marketed, and sold the 3DMax™ Light Mesh, 3DMax™ Mesh, Bard® Mesh Dart, Bard® Mesh (formally known as Marlex), Composix™ Mesh, Composix™ E/X Mesh,

Composix® Kugel® Hernia Patch, Composix™ L/P Mesh, Kugel® Hernia Patch, Modified Kugel® Hernia Patch, PerFix™ Plug, PerFix™ Light Plug, SpermaTex™ Mesh, Ventralight™ ST Mesh, Ventralex™ Hernia Patch, Ventralex™ ST Hernia Patch, Ventrío™ Hernia Patch, Ventrío™ ST Hernia Patch, and Visilex™ Mesh for use by prescribing physicians in accordance with its accompanying labeling information. Davol admits that at various times it manufactured, marketed, and sold the Sepramesh™ IP Composite for use by prescribing physicians in accordance with its accompanying labeling information. Defendants deny that the warnings for these products were inadequate.

238. The allegations in Paragraph 238 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 238 of the Master Complaint.

239. The allegations in Paragraph 239 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 239 of the Master Complaint.

240. The allegations in Paragraph 240 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 240 of the Master Complaint.

241. The allegations in Paragraph 241 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 241 of the Master Complaint.

242. The allegations in Paragraph 242 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 242 of the Master Complaint.

243. The allegations in Paragraph 243 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 243 of the Master Complaint.

244. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 244 of the Master Complaint and therefore deny the same.

245. The allegations in Paragraph 245 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 245 of the Master Complaint.

246. The allegations in Paragraph 246 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 246 of the Master Complaint.

247. The allegations in Paragraph 247 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 247 of the Master Complaint.

**COUNT XIV
FRAUDULENT CONCEALMENT**

248. In response to Paragraph 248 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

249. The allegations in Paragraph 249 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 249 of the Master Complaint.

250. The allegations in Paragraph 250 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 250 of the Master Complaint.

251. The allegations in Paragraph 251 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 251 of the Master Complaint.

252. The allegations in Paragraph 252 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 252 of the Master Complaint.

253. The allegations in Paragraph 253 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 253 of the Master Complaint.

254. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 254 of the Master Complaint and therefore deny the same.

255. The allegations in Paragraph 255 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 255 of the Master Complaint.

256. The allegations in Paragraph 256 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 256 of the Master Complaint.

257. The allegations in Paragraph 257 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 257 of the Master Complaint.

258. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 258 of the Master Complaint and therefore deny the same.

259. The allegations in Paragraph 259 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 259 of the Master Complaint.

260. The allegations in Paragraph 260 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 260 of the Master Complaint.

261. The allegations in Paragraph 261 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 261 of the Master Complaint.

262. The allegations in Paragraph 262 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 262 of the Master Complaint.

263. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 263 of the Master Complaint and therefore deny the same.

264. The allegations in Paragraph 264 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 264 of the Master Complaint.

265. The allegations in Paragraph 265 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 265 of the Master Complaint.

266. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 266 of the Master Complaint and therefore deny the same.

267. The allegations in Paragraph 267 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 267 of the Master Complaint.

268. The allegations in Paragraph 268 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 268 of the Master Complaint.

269. The allegations in Paragraph 269 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 269 of the Master Complaint.

270. The allegations in Paragraph 270 of the Master Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 270 of the Master Complaint.

COUNT XV WRONGFUL DEATH

271. In response to Paragraph 271 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

272. The allegations in Paragraph 272 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 272 of the Master Complaint.

273. The allegations in Paragraph 273 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 273 of the Master Complaint.

274. The allegations in Paragraph 274 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 274 of the Master Complaint.

275. The allegations in Paragraph 275 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 275 of the Master Complaint.

**COUNT XVI
LOSS OF CONSORTIUM**

276. In response to Paragraph 276 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

277. The allegations in Paragraph 277 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 277 of the Master Complaint.

278. The allegations in Paragraph 278 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 278 of the Master Complaint.

279. The allegations in Paragraph 279 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 279 of the Master Complaint.

280. The allegations in Paragraph 280 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 280 of the Master Complaint.

281. The allegations in Paragraph 281 of the Master Complaint are conclusions of law, tied to the filing of a Short Form Complaint, and no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 281 of the Master Complaint.

**COUNT XVII
PUNITIVE DAMAGES**

282. In response to Paragraph 282 of the Master Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

283. Defendants deny the allegations in Paragraph 283 of the Master Complaint.

284. Defendants deny the allegations in Paragraph 284 of the Master Complaint.

285. Defendants deny the allegations in Paragraph 285 of the Master Complaint.

286. Defendants deny the allegations in Paragraph 286 of the Master Complaint.

287. Defendants deny the allegations in Paragraph 287 of the Master Complaint.

288. Defendants deny the allegations in Paragraph 288 of the Master Complaint.

289. Defendants deny the allegations in Paragraph 289 of the Master Complaint.

290. Defendants deny the allegations in Paragraph 290 of the Master Complaint.

291. Defendants deny the allegations in Paragraph 291 of the Master Complaint.

SEPARATE DEFENSES

1. The Master Complaint, in whole or part, fails to state a claim or cause of action against Defendants upon which relief can be granted.

2. The doctrines contained in Restatement (Second) of Torts § 402A, Comment k, bar Plaintiff's claims against Defendants in whole or in part.

3. The doctrines contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar Plaintiff's claims against Defendants in whole or in part.

4. The doctrine of spoliation and the failure to properly preserve evidence necessary to the determination of the alleged claims bar Plaintiff's claims against Defendants in whole or in part.

5. The doctrine of *forum non conveniens* applies to this case.

6. Plaintiff's claims against Bard fail for lack of personal jurisdiction for any Plaintiff whose state of residency is outside of New Jersey.

7. Plaintiff's claims against Davol fail for lack of personal jurisdiction for any Plaintiff whose state of residency is outside of Rhode Island.

8. Defendants reserve all rights under *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

9. Applicable statutes of limitations, statute of repose, and the doctrine of laches bar Plaintiff's claims in whole or in part.

10. Plaintiff's, or Plaintiff's agents', including Plaintiff's physicians', misuse or abnormal use of the product or failure to follow instructions bar Plaintiffs' claims in whole or in part.

11. If Plaintiff used a product sold by Defendants, then Plaintiff's claims are barred, in whole or in part, because Plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

12. Any alleged negligent or culpable conduct of Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

13. If Plaintiff sustained any damages or injuries, which is denied, then such damages and injuries were caused or contributed to by the acts, omissions or fault of Plaintiff, including

contributory negligence, contributory fault, comparative fault, assumption of the risk, or failure to mitigate damages.

14. If Plaintiff used a product sold by Defendants, Plaintiff used the product for off-label purposes, which bars the Plaintiff's claims.

15. The learned intermediary doctrine bars Plaintiff's claims.

16. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

17. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

18. Plaintiff's claims are preempted, in whole or in part, by applicable federal law.

19. Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of conduct of Plaintiffs, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiffs' pre-existing medical conditions.

20. If Plaintiff suffered injuries or damages as alleged, which is denied, such injuries or damages resulted from acts or omissions of persons or entities for which Defendants are neither liable nor responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by Defendants. Such acts or

omissions on the part of other persons or entities, such diseases and/or such causes constitute an independent, intervening and sole proximate cause of Plaintiff's alleged injury or damages.

21. Defendants state that if Plaintiff sustained any damages or injuries, which is specifically denied, such damages or injuries were caused by the acts, omissions or fault of Plaintiff or others, for whose conduct these Defendants are not responsible; accordingly, they are entitled to an assessment of the relative degree of fault for all such persons and entities.

22. Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injuries, if caused by Defendants' product(s), which is denied, were the result of Plaintiff's own idiosyncratic reactions.

23. Plaintiff failed to mitigate damages, which limits Plaintiff's recovery, if any, in whole or in part.

24. Defendants have no legal relationship or privity with Plaintiff and owe no duty to Plaintiff by which liability could be attributed to it.

25. Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff. If any such warranties were made, whether express or implied, which Defendants specifically deny, then Plaintiff failed to give notice of any breach thereof. Moreover, Defendants effectively and fully disclaimed any warranty, express or implied, in the sale of any product for which they are responsible in this matter.

26. Plaintiff's claims are barred in whole or in part by Plaintiff's own comparative negligence.

27. Plaintiff's recovery, if any, shall be reduced by those payments that Plaintiff received from collateral sources.

28. If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by Defendants' product.

29. At the time the product(s) at issue left the custody and control of Defendants, there was no defect in said product(s) that either caused or contributed to any injuries or damages that Plaintiff may have suffered, if any.

30. At the time Plaintiff's received the product(s), Defendants did not design, manufacture, or sell the product(s).

31. Plaintiff fails to allege facts to state a cause of action against Defendants to support a claim for negligent infliction of emotional distress.

32. Plaintiff fails to allege facts to state a cause of action against Defendants to support a claim for intentional infliction of emotional distress.

33. Plaintiff fails to allege facts to state a cause of action against Defendants to support a claim for breach of implied warranty.

34. To the extent Plaintiff is required to plead his claims with sufficient particularity to satisfy the requirements of Federal Rule of Civil Procedure 9, Plaintiff has failed to do so and Plaintiff's claims must be dismissed. Plaintiff has not pled the fraud claim with particularity as required by Federal Rule of Civil Procedure 9 and that claim must be dismissed.

35. The applicable state and federal law, including *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), bars Plaintiff's alleged claims for punitive or exemplary damages. Permitting recovery of punitive or exemplary damages in this case would violate Defendants' rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution, and related provisions of the United States Constitution, as well as the due process guarantees embodied in state constitutions.

36. To the extent that the applicable state law permits the jury and Courts to measure punitive or exemplary damages by the net worth or financial status of Defendants and imposes greater punishment on defendants with greater net worth, such an award would be unconstitutional because it permits arbitrary punishment, allows bias and prejudice to infect the verdict, and allows dissimilar treatment of similarly situated defendants, all in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the similar provisions in state constitutions.

37. To the extent Plaintiff's Master Complaint seeks punitive damages, such claims are barred because Plaintiff has failed to allege conduct warranting the imposition of punitive damages under the applicable state law and/or other applicable laws.

38. To the extent Plaintiff's Master Complaint seeks punitive damages, applicable federal law preempts any such claim, in whole or in part.

39. Depending on the specific theory advanced by any given plaintiff at trial, such claims may be impliedly preempted.

40. Plaintiff's claims are, in whole or in part, subject to adjudication under the laws of states or jurisdictions other than Ohio.

41. Defendants hereby give notice that state law applicable to the claims of each Plaintiff on a case by case basis may provide additional defenses, which Defendants reserve their right to amend this Master Answer or Short Form Adoption By Reference Answer To Plaintiffs' Short Form Adoption By Reference Complaint to assert such defenses.

42. Defendants hereby give notice that state law applicable to an individual Plaintiff's case may not recognize a claim asserted in the Master Complaint or provide a defense to it.

43. Defendants hereby give notice that they intend to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserve their right to amend this Master Answer or Short Form Adoption By Reference Answer To Plaintiffs' Short Form Adoption By Reference Complaint to assert such defenses.

WHEREFORE, Defendants Davol Inc. and C. R. Bard, Inc. demand judgment in their favor and against Plaintiffs, dismissing Plaintiffs' Master Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY TRIAL DEMAND

PLEASE TAKE NOTICE that answering Defendants hereby demand a trial by jury as to all issues.

January 2, 2019

Respectfully submitted,

/s/ William D. Kloss, Jr.

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Inc. and Davol Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on January 2, 2019, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

/s/ William D. Kloss, Jr.
*Liaison Counsel for Defendants C. R. Bard,
Inc. and Davol Inc.*